OBJECTIVES: To conduct a study to assess value perceptions and the evidence needs for key stakeholders of medical product manufacturers, including payers and employers. This study was a structured, qualitative assessment of influential U.S. health plans and companies. **METHODS:** Telephone survey interviews were used to collect data from fifteen private U.S. payer representatives and payer-related experts. Phone and in-person interviews were conducted with twenty-six U.S. employer representatives. Working behavioral assumptions were constructed for the payer and employer groups, and stakeholder-specific discussion guides were used to facilitate the survey interviews. **RESULTS:** The top payer findings suggest that health plans are most interested in clinical safety, efficacy, and effectiveness evidence. Payers' demands are increasing for more clinical utility and clinical performance studies providing comparative information for medical products. Cost and cost-effectiveness were identified as important but secondary considerations for coverage and reimbursement decisions. The employers surveyed exhibited substantial diversity in their approach to providing health care benefits for employees. The majority of employers and payers reported that consumer-directed health care (CDHC) plans are increasing in scope and will play a larger role moving forward. Most reported that the effects of CDHC on costs and long-term health outcomes are unclear. Recent trends associated with health care costs increasing faster than inflation contribute to employers' difficulty with defining "value in health care" and to their challenges associated with evaluating return on investment for health care expenditures. **CONCLUSION:** U.S. employers and payers are struggling with clearly defining the concept of medical product value. Payers rely on phase III randomized controlled trials as their primary evidence source for covering medical products, yet request additional post-marketing comparative studies. Employers are largely engaged in cost-shifting to employees and are trying to select younger and healthier workforces to reduce their health care expenditures.

PHP11

THE VOLUNTARY INCENTIVE STRUCTURE OF PEDIATRIC EXCLUSIVITY AND ITS IMPACTS ON PHARMACEUTICAL INDUSTRY BEHAVIOR AND GENERIC DRUG ENTRIES

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OBJECTIVES: The FDA Modernization Act of 1997 created a six-month of market exclusivity extension in exchange for pharmaceutical companies' pediatric studies for the drugs of potential benefits to the pediatric population. This study examines how the voluntary incentive structure of the exclusivity has impacted on the pharmaceutical industry's efforts to obtain the exclusivity and how the rule has been used to delay generic entries for the exclusivity period. **METHODS:** By using 63 drugs whose patent expired between 1999 and 2003, obtained from the FDA, several descriptive analyses were performed. The percentage of drugs with pediatric exclusivity was described by several important factors, especially focusing on main use of the drugs. Next, all the drugs were divided into two groups—drugs with exclusivity vs. no exclusivity—and then generic competition degree was presented by each group for two years following the initial patent expiration of each drug. **RESULTS:** A bigger firm was good at filing the exclusivity that needs additional clinical study ($p < 0.05$). The competition level in each drug's therapeutic class was positively associated with having the exclusivity. The drugs with exclusivities were more likely to treat chronic conditions that include many blockbuster drugs. The firms have applied for pediatric extension over the drugs with larger market size ($p < 0.01$). For pediatric exclusivity group, there were no generic competitors until six months and then there was a dramatic increase of generic entries after the exclusivity expired whereas no-pediatric group didn't show notable increasing trend during the observation period. **CONCLUSION:** The market size of a drug was the most important factor to acquire the pediatric exclusivity that has been a tool for an originator firm to delay generic competition. It implies the incentive structure based on willingness of industry has not always achieved the primary goal of "safety of children".

PHP12

DIFFERENCES IN CHRONIC DISEASE CARE OF PRE_MEDICARE INDIVIDUALS BETWEEN METROPOLITAN AND NON-METROPOLITAN SETTINGS

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OBJECTIVES: Differences between metropolitan and non-metropolitan setting in the management of chronic conditions in patients 55 to 64 years of age can result in higher morbidity rates in non-metropolitan areas. We will look at the association between the geographic setting and indicators of care management for visits in this population. **METHODS:** Data from the National Ambulatory Medical Care and National Hospital Ambulatory Medical Care (outpatient department) surveys were combined for years 2001 to 2004. NAMCS and NHAMCS collect visit data from medical records of randomly selected physician offices, hospital outpatient departments, and hospital emergency departments during randomly selected time periods through the year. A metropolitan area is an urban area with a core population of at least 50,000. Visit data were weighted by the inverse of selection probability and used to provide annual average estimates. Visits having diagnoses codes for hypertension, diabetes, COPD, heart disease, stroke, and cancer were selected based on the ICD-9-CM codes. Number of chronic diseases, medications mentioned, therapeutic and preventive services performed, and diagnostic procedures ordered per visit were compared between metropolitan and non-metropolitan settings. SUDAAN software was used to develop a Poison regression model to perform the comparisons. Source of payment, gender, and race for patients were included in the model as covariates. The effect of the number of previous visits on the outcomes will be examined in future. **RESULTS:** Although rural visits had a higher number of chronic conditions (1.14 vs. 1.11, $p < 0.05$), they had a smaller number of therapeutic and preventive services performed per visit (1.22 vs. 2.73, $p < 0.01$) and had a lower number of diagnostic and screening procedures ordered per visit (2.61 vs. 3.04, $p < 0.05$). **CONCLUSION:** The differences in care management in the years preceding Medicare eligibility could have implications for utilization of services once this population enrolls in Medicare.

PHP13

THE TRENDS IN PRESCRIBING OF HERBAL MEDICINES IN AMBULATORY SETTINGS IN THE UNITED STATES 1993–2004

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OBJECTIVES: The use and awareness of herbal medicines has been on the rise. Although most of these products are over the counter (OTC), it is less known how often they are recommended during office-based physician visits. Purpose: The objective of this study was to investigate the trends in prescribing of herbal medicines in the ambulatory medical setting in the U.S. **METHODS:** This study was a retrospective analysis of the National Ambulatory Medical Care Survey (NAMCS) and